

ACEPHEN - acetaminophen suppository
Cosette Pharmaceuticals, Inc.

Pediatric AcephenTM Acetaminophen Suppositories USP, 120 mg

ACTIVE INGREDIENT (in each rectal suppository)

Acetaminophen 120 mg

PURPOSE

Pain reliever/fever reducer

USES

temporarily

- reduces fever
- relieves minor aches, pains, and headache

WARNINGS

For rectal use only

Liver Warning: This product contains acetaminophen. Severe liver damage may occur if your child inserts

- more than 5 suppositories in 24 hours, which is the maximum daily amount
- with other drugs containing acetaminophen

Allergy alert: Acetaminophen may cause severe skin reactions.

Symptoms may include:

- skin reddening
- blisters
- rash

If a skin reaction occurs, stop use and seek medical help right away.

Do not use

- if your child is allergic to acetaminophen
- with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist.

Ask a doctor before use if your child has liver disease

Ask a doctor or pharmacist before use if your child is taking the blood thinning drug warfarin

Stop use and ask a doctor if

- fever lasts more than 3 days (72 hours), or recurs
 - you need to use this product for pain for more than 5 days continuously
- Severe or recurrent pain, or high or continued fever may indicate a serious illness.

Keep out of reach of children.

If swallowed or in case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical in case of overdose for children even if you do not notice any signs

or symptoms.

Directions

This product does not contain directions or complete warnings for adult use.

- **do not use more than directed**
- remove foil wrapper
- insert suppository well up into rectum
- children 3-6 years
 - 1 suppository every 4 to 6 hours while symptoms persist
 - do not exceed 5 suppositories in any 24-hour period
- children under 3 years: ask a doctor

Other Information

- for your safety, suppositories are packaged in tamper-evident sealed foil. Do not use if foil is torn or open.
- store at 8°-25°C (46°-77°F)

Inactive ingredients

butylated hydroxyanisole, butylated hydroxytoluene, glyceryl stearate, hydrogenated vegetable oil, polyethylene glycol 100 stearate, polysorbate 80

Questions?

call **1-800-922-1038**

Monday-Friday 9am-4pm EST

PRINCIPAL DISPLAY PANEL




NDC 0713-0118-50

G&W Pediatric ACEPHEN™ Acetaminophen Suppositories USP 120 mg
ASPIRIN FREE

Pain Reliever • Fever Reducer

50 Rectal Suppositories

08/2013

Drug Facts Active ingredient (in each rectal suppository) Acetaminophen 120 mg Purpose Pain reliever/fever reducer Uses temporarily • reduces fever • relieves minor aches, pains, and headache Warnings For rectal use only Liver warnings: This product contains acetaminophen. Severe liver damage may occur if your child inserts more than 5 suppositories in 24 hours, which is the maximum daily amount. • with other drugs containing acetaminophen Allergy alert: acetaminophen may cause severe skin reactions. Symptoms may include: • skin redness • hives • rash If a skin reaction occurs, stop use and seek medical help right away. Do not use • if your child is allergic to acetaminophen • with any other drug containing acetaminophen (prescription or nonprescription). If you are not sure whether a drug contains acetaminophen, ask a doctor or pharmacist. Ask a doctor before use if your child has: liver disease Ask a doctor or pharmacist before use if your child is: taking the blood thinning drug warfarin Stop use and ask a doctor if: • fever lasts more than 3 days • you need to use this product for pain for more than 5 days continuously Severe or recurrent pain, or high or continued fever may indicate a serious illness. Keep out of reach of children. If swallowed or in case of overdose, get medical help or contact a Poison Control Center right away. Quick medical attention is critical in case of overdose for children even if you do not notice any signs or symptoms.	Drug Facts (continued) Directions This product does not contain directions or complete warnings for adult use. • do not use more than directed • remove foil wrapper • insert suppository well up into rectum • children 3-6 years • 1 suppository every 4 to 6 hours while symptoms persist • do not exceed 5 suppositories in any 24-hour period • children under 3 years: ask a doctor Other information • for your safety, suppositories are packaged in tamper-evident sealed foil. Do not use if foil is torn or open. • store at 8°-25°C (46°-77°F) Inactive ingredients butylated hydroxyanisole, butylated hydroxytoluene, glyceryl stearate, hydrogenated vegetable oil, polyethylene glycol 100 stearate, polysorbate 80 Questions? call 1-800-922-1038 Monday-Friday 9am-4pm EST  G&W Laboratories, Inc. 111 Coolidge Street South Plainfield, NJ 07080 Visit our website @ www.gwlabs.com	 NDC 0713-0118-50 Pediatric ACEPHEN™ ACETAMINOPHEN SUPPOSITORIES USP ASPIRIN FREE 120 mg Pain Reliever • Fever Reducer 50 RECTAL SUPPOSITORIES	 TAMPER-EVIDENT: Individually sealed in foil for your protection. Do not use if foil is torn or open.
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ACEPHEN

acetaminophen suppository

Product Information

Product Type	HUMAN OTC DRUG	Item Code (Source)	NDC:0713-0118
Route of Administration	RECTAL		

Active Ingredient/Active Moiety

Ingredient Name	Basis of Strength	Strength
ACETAMINOPHEN (UNII: 362O9ITL9D) (ACETAMINOPHEN - UNII:362O9ITL9D)	ACETAMINOPHEN	120 mg

Inactive Ingredients

Ingredient Name	Strength
BUTYLATED HYDROXYANISOLE (UNII: REK4960K2U)	
BUTYLATED HYDROXYTOLUENE (UNII: 1P9D0Z171K)	
GLYCERYL MONOSTEARATE (UNII: 230OU9XXE4)	
HYDROGENATED COCONUT OIL (UNII: JY81OXM1OM)	
PEG-8 STEARATE (UNII: 2P9L47VI5E)	
POLYSORBATE 80 (UNII: 6OZP39ZG8H)	

Packaging

#	Item Code	Package Description	Marketing Start Date	Marketing End Date
1	NDC:0713-0118-12	12 in 1 BOX; Type 0: Not a Combination Product	01/01/1982	
2	NDC:0713-0118-01	100 in 1 BOX; Type 0: Not a Combination Product	01/01/1982	
3	NDC:0713-0118-50	50 in 1 BOX; Type 0: Not a Combination Product	01/01/1982	

Marketing Information

Marketing Category	Application Number or Monograph Citation	Marketing Start Date	Marketing End Date
NDA	NDA018060	01/01/1982	

Labeler - Cosette Pharmaceuticals, Inc. (116918230)

Registrant - Cosette Pharmaceuticals, Inc. (116918230)

Establishment

Name	Address	ID/FEI	Business Operations
Cosette Pharmaceuticals, Inc.		116918230	analysis(0713-0118) , manufacture(0713-0118) , label(0713-0118) , pack(0713-0118)